

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The comparison between chlorhexidine solution and toothbrush in prevention of oral lesions in patients hospitalized in intensive care unit

Protocol summary

Summary

The aim of this study is comparing the effects of toothbrush (intervention) and Chlorhexidine solution (control) for preventing of oral lesions. In this study 30 intubated patients who are admitted in ICU ward of Shahid Beheshti Hospital, will be randomly divided into two groups. Technique, timing and frequency of mouthwash application is similar in both groups. In the intervention group, internal and external surfaces of the teeth and gums are rotationally brushed by using a soft kid's toothbrush and half a centimeter toothpaste. This action is done every 8 hours during 4 days. Control group members wash their mouths with 0.2 % (Zero point two percent) chlorhexidine solution. This action is also done every 8 hours for 2 minutes during 4 days for control group. patients with age of 18-65 years old who are admitted in ICU Less than 6 hours will be eligible to the study. Transferring from ICU or death before the completion of intervention; allergy to mouthwash; history or current chronic or immune system diseases are exclusion criteria. During the study the mouth is checked three times a day before mouth intervention for four days, the patient's mouth is checked with Boas and Muroid plaque score(MPS) and those features are recorded in the checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012216309N1**

Registration date: **2014-04-18, 1393/01/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-18, 1393/01/29

Registrant information

Name

Mohammad Alinejad Moghadam

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 57 1444 5648

Email address

mohammadalinejad23@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research of Sabzevar University of Medical Sciences

Expected recruitment start date

2013-11-15, 1392/08/24

Expected recruitment end date

2014-01-18, 1392/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between chlorhexidine solution and toothbrush in prevention of oral lesions in patients hospitalized in intensive care unit

Public title

Comparison the effect of chlorhexidine solution and toothbrush in the prevention of oral lesions

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria: Having oral endotracheal tube, being 18-65 years old ,The absence of wound, infection

and oral trauma, Not having diseases like hepatitis B and HIV; Not having any symptoms or antecedent of aspiration, serious problems, and artificial teeth. Exclusion criteria are: death at the time of the study, Separation from mechanical ventilation at the time of the study; View apparent aspiration, existence of allergic reactions; restrictions on procedures and aspiration risk.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this double blind randomized clinical trial samples in the two groups will be labeled by letters A, B and The researcher who measures the Implications of the study is unaware of the intervention groups. Patients are also blind as they are unconscious at the time of intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar

City

Sabzevar

Postal code

9613873136

Approval date

2013-11-12, 1392/08/21

Ethics committee reference number

medsab.Rec.92.3

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

k05

ICD-10 code description

Gingivitis and periodontal diseases

2

Description of health condition studied

Other diseases of lip and oral mucosa

ICD-10 code

K13

ICD-10 code description

Other diseases of lip and oral mucosa

3

Description of health condition studied

Diseases of tongue

ICD-10 code

K14

ICD-10 code description

Diseases of tongue

Primary outcomes

1

Description

oral health

Timepoint

Daily for 4 days

Method of measurement

Beck Oral Assessment Scale and Mucosal Plaque Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After approving of the study by sciences vice chancellor of Sabzevar University of medical sciences and completing the written consent forms by all participants in the study, Patients are divided randomly into two equal groups: 15 patients in intervention and 15 in control group. In the intervention group, internal and external surfaces of the teeth and gums are rotationally brushed by using a soft kid's toothbrush and half a centimeter toothpaste .This action is done every 8 hours during 4 days.

Category

Prevention

2

Description

Control group: control group members wash their mouth with 0.2 % (zero point two percent) chlorhexidine solution. This action is also done every 8 hours for 2 minutes during 4 days but for control group. Also, the observation of mouth is done by BOAS and MPS every 8 hours before utilizing a mouthwash (before washing mouth by chlorhexidine solution). Then, we record it in a checklist.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Beheshti Hospital

Full name of responsible person

Mohammad Alinejad Moghadam

Street address

Sabzevar University of Medical Sciences- SHaheed Beheshti Hospital

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research of Sabzevar University of Medical Sciences

Full name of responsible person

Moosa Reza Tadayonfar

Street address

School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar

City

Sabzevar

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for Research of Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Alinejad Moghadam

Position

Student of MSc Nursing

Other areas of specialty/work

Street address

Faculty of nursing and midwifery , next to the police station at SHahroud road, Sabzevar

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Email

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Zahra Estaji

Position

MSc./Member of Faculty

Other areas of specialty/work

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Person responsible for updating data

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Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty